

K07 3065

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### 510(k) Summary

Device Proprietary Name: OsteoMed Metatarsal  
Resurfacing Implant System

Device Common Name: Metatarsal Resurfacing Implant  
System

Classification Name: KWD, Prosthesis, Toe, Hemi-,  
Phalangeal

Name of Submitter: OsteoMed L. P.  
3885 Arapaho Road  
Addison, Texas 75001  
Phone: (972) 677-4600  
Fax: (972) 677-4601

Contact Person: Piedad Peña

Date Prepared: February 8, 2008

#### Summary:

This submission describes the OsteoMed Metatarsal Resurfacing Implant System, a hemi arthroplasty implant system, for the metatarsophalangeal (MTP) joint for use in treatment of patients with degenerative and post-traumatic arthritis in the MTP joints in the presence of good bone stock and integrity of the phalangeal base, along with the following clinical conditions; hallux limitus, hallux valgus, hallux rigidus, and an unstable or painful MTP joint. OsteoMed Metatarsal Resurfacing Implant is intended for single use only.

The OsteoMed Metatarsal Resurfacing Implant is a one piece implant designed to replace the distal head of the metatarsal and provides a smooth articular surface for the adjacent phalangeal base. The implant is available in several sizes in direct proportion to the anatomic construct of the metatarsal head. Primary fixation is intended to be used with bone cement or press fit without bone cement.

Equivalence for this device is based on similarities in intended use, materials, design and operational principle to the Arthrosurface CAP Great Toe Resurfacing Hemi- Arthroplasty Implant (K031859) and CAP Prosthetic 7.0mm MTP Resurfacing Hemi- arthroplasty (K063370), Vilex Met-Head Resurfacing Hemi- Arthroplasty Implant (K070052), OsteoMed 1<sup>st</sup> MPJ Hemi Implant System (K060536) and ReFlexion Great Toe System (K922211), and BioPro Hemi MPJoint (K041595).

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Due to the similarity in intended use, materials, design and operational principle to the predicate devices, OsteoMed believes that the OsteoMed Metatarsal Resurfacing Implant System does not raise any new safety or effectiveness issues.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 21 2008

OsteoMed L.P.  
% Ms. Piedad Peña  
Regulatory Affairs Specialist  
3885 Arapaho Road  
Addison, TX 75001

Re: K073065  
Trade/Device Name: OsteoMed Metatarsal Resurfacing Implant System  
Regulation Number: 21 CFR 888.3730  
Regulation Name: Toe joint phalangeal (hemi-toe) polymer prosthesis  
Regulatory Class: Class II  
Product Code: KWD  
Dated: February 8, 2008  
Received: February 11, 2008

Dear Ms. Peña:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Piedad Peña

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

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### Indications for Use

510(k) Number (if known): \_\_\_\_\_

Device Name: OsteoMed Metatarsal Resurfacing Implant System

#### Indications for Use:

The OsteoMed Metatarsal Resurfacing Implant, a hemi-arthroplasty implant for the metatarsophalangeal (MTP) joint, is indicated for use in the treatment of patients with degenerative and post-traumatic arthritis in the MTP joint in the presence of good bone stock and integrity of the phalangeal base, along with the following clinical conditions; hallux limitus, hallux valgus, hallux rigidus, and an unstable or painful MTP joint.

The OsteoMed Metatarsal Resurfacing Implant is intended to be used with bone cement or press fit without bone cement.

The OsteoMed Metatarsal Resurfacing Implant is intended for single use only.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of General, Restorative, Page 1 of 1  
and Neurological Devices

(Posted November 13, 2003)

510(k) Number K073065